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| 10/020,635   | 12/14/2001  | Ira L. Shapira       | 28947/3541 1B       | 9711             |
| 4743   | 7590        | 05/05/2004           | EXAMINER            |                  |
| MARSHALL, GERSTEIN & BORUN LLP<br>6300 SEARS TOWER<br>233 S. WACKER DRIVE<br>CHICAGO, IL 60606 |             |                      | DAVIS, DANIEL J     |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 3731                | 5                |

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/020,635

Applicant(s)

SHAPIRA, IRA L.

Examiner

D. Jacob Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 17-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2-4.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-16, drawn to an apparatus for extracting bone, classified in class 606, subclass 180.
- II. Claims 17-26, drawn to a method for extracting and collecting bone, classified in class 606, subclass 80.
- III. Claims 27-32, drawn to a shield, classified in class 606, subclass 96.
- IV. Claims 33-37, drawn to a bone implant, classified in class 606, subclass 86.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group II and Group I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case collecting the removed bone may be accomplished by hand.

Inventions Group I, Group III and Group IV are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. For example, the invention of Group I has separate utility such as drilling bone without the shield or bone implant.

See MPEP § 806.05(d). The shield of Group II can be used as a funnel to channel fluid to a desired location. Group IV, the bone implant, can be used as a guide to limit the movement of other types of surgically inserted tools.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Brent Matthias on April 20, 2004, a provisional election was made without traverse to prosecute the invention of Group I, claims 1-16. Affirmation of this election must be made by applicant in replying to this Office action. Claims 17-37 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Harrel (US 5,122,153). Harrel discloses an apparatus (Fig. 6) for extracting bone

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material comprising a housing 96 defining a cavity within element 100, a passageway 108, and a "flexible" shaft 102, an actuator (col. 3, lines 29-31), an abrading head/bur 112. Col. 3, lines 47-50 disclose the relationship between the passageway, a vacuum source, a container, and a suction tube 36 (Fig. 1).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(c) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-4 are rejected under Harrel (US 5,122,153) in view of Bonutti (US 5,269,785). Harrel discloses an apparatus (Fig. 6) extracting bone material comprising a housing 96 defining a cavity within element 100, a passageway 108, and a shaft 102 with an abrading head/bur 112. Col. 3, lines 47-50 disclose the relationship between the passageway, a vacuum source, a container, and a suction tube 36 (Fig. 1).

Harrel discloses the conduit in the same lumen as the cavity but fails to disclose "a conduit extending through the shaft and abrading head." Nevertheless, in Fig. 6, Bonutti teaches a conduit within a shaft and bur head having a suction system to remove bone. It would have been obvious to one of ordinary skill in the art at the time the invention was made to switch the conduit from the outside of the shaft and head to the inside of the shaft and head as taught by Bonutti, because a mere reversal of the essential working parts of a device involves only routine skill in the art.

Claim 5 is rejected under 35 U.S.C. 103(c) as being obvious over Harrel in view of Bonutti and in further view of Abbott (US 4,176,453). Harrel and Bonutti fail to disclose the housing defining an irrigation second passageway. Nevertheless, Abbott teaches a housing 14 (Fig. 2) defining an irrigation second passage 36. Inherently, the irrigation second passageway is in communication with a source of irrigation fluid. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the Harrel/Bonutti device as taught by Abbott to further include a housing 14 defining an irrigation second passage 36 in order to irrigate a site.

Claims 6-9 are rejected under 35 U.S.C. 103(c) as being obvious over Del Rio et al. (US 5,601,560) in view of Harrel (US 5,122,153). Del Rio discloses an apparatus for removing bone material (Figs. 1-4) comprising a housing 12 and 18 defining a cavity, a drive member 104, 106 and 118, a shaft 24, and an abrading head/bur 22. As illustrated in Figs. 2 and 4, the shaft is releasably connected to the drive. The drive member comprises a rotating shaft 104.

Del Rio fails to disclose that the housing defines a passageway for transporting bone material to a collection device, and a suction tube. Nevertheless, in Fig. 6, Harrel teaches a housing 96 defining both a cavity (defined within element 100) and a passageway 108. The passageway is connected to a suction tube that is not illustrated (col. 7, lines 10-13). In turn the suction tube is attached "to a source of suction, via an intermediate containment vessel [a container] (not shown) for holding an accumulation

of tissue removed" (col. 3, lines 47-50). The suction removes ablated tissue material. Therefore, it would have been obvious to include a suction component to the Del Rio device including suction system comprising a housing defining a passageway, a container, a suction tube, and a vacuum source to remove the ablated tissue.

Claim 10 is rejected under 35 U.S.C. 103(c) as being obvious over Del Rio in view of Harrel and in further view of Abbott (US 4,176,453). Del Rio and Harrel fail to disclose the housing defining an irrigation second passageway. Nevertheless, Abbott teaches a housing 14 (Fig. 2) defining an irrigation second passage 36. Inherently, the irrigation second passageway is in communication with a source of irrigation fluid. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the Harrel/Bonutti device as taught by Abbott to further include a housing 14 defining an irrigation second passage 36 in order to irrigate a site.

Claims 11, 12 and 14 are rejected under 35 U.S.C. 103(c) as being obvious over Harrel in view of Keith. Harrel fails to disclose that the shaft 102 may be made of a coil. Nevertheless, Keith teaches the use of a tightly wound coil shaft 42 (col. 9, lines 45-49) to increase the shaft flexibility. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Harrel shaft to be a tightly wound coil taught by Keith, to increase the flexibility of the shaft.

Claims 11, 13 and 14 are rejected under 35 U.S.C. 103(c) as being obvious over Harrel in view of Barber (US 4,541,423). Harrel fails to disclose that the shaft is pre-stressed to bend in a predetermined direction. Barber teaches a conformable sheath 11 through which a highly flexible shaft 12 is extended in order to guide the drill through a predetermined curvature. The sheath 11 pre-stresses the shaft 12 before application, causing the shaft to bend. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Harrel device to have a pre-stressed bend in a predetermined direction, as taught by Barber. This enables the device to follow a curved cutting path, or to cut tissue in difficult to reach locations.

Claims 11, 14 and 15 are rejected under 35 U.S.C. 103(c) as being obvious over Harrel in view of Bonutti. Harrel discloses the passageway 108 in communication with the cavity within element 100. The cavity is used to aspirate tissue. The patent fails to disclose that the aspirating conduit resides within the shaft and head. In Fig. 6, Bonutti teaches a conduit within a shaft and bur head having a suction system to remove bone. It would have been obvious to one of ordinary skill in the art at the time the invention was made to switch the conduit from the outside of the shaft and head to the inside of the shaft and head as taught by Bonutti, because a mere reversal of the essential working parts of a device involves only routine skill in the art.

Claims 11, 14, and 16 are rejected under 35 U.S.C. 103(c) as being obvious over Harrel in view of Del Rio. Harrel fails to disclose the shaft second end is releasably



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connected to a drive member. Nevertheless, Del Rio teaches a drive member 104, 106 and 118, which releasably connects a shaft 24. The releasable connection enables the attachment and removal of various sized tool bits (col. 1, lines 38-41). Both the drive member and the shaft are within the housing. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the Harell shaft to be releasably connected to a drive member, as taught by Del Rio, to interchange various sized tool bits.


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Jacob Davis whose telephone number is (703) 305-1232. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DJD  
April 26, 2004

  
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